REMARKS

Claims 17-19, 27, 45-47 and 50-58 are pending herein. Support for these claims can be found throughout the specification and drawings. No new matter has been added.

The Examiner has rejected Claims 17-19, 27 and 45-47 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Examiner asserts that Claim 27 is incomplete for omitting an essential step, specifically, the step of holding the free end of the length of natural tissue when pulling the drawstring to cause folding of the tissue. By way of responding to this ground of rejection, applicants have amended Claim 27 to recite, in step (c), "pulling the drawstring while the tissue remains essentially in place." Thus, by its express terms, the method of amended Claim 27 cannot result in the implanted tissue being pulled to any appreciable extent in the drawstring-pulling direction.

The examiner has rejected Claims 17, 27 and 45-47 under 35 U.S.C. § 103(a) as being unpatentable for obviousness over Lambrecht et al. (2002/151979). The Examiner applies Lambrecht et al. as follows:

> ...Fig. 49G illustrates an intervertebral disc implant **400** having a length and a first straight configuration with a drawstring **406** attached thereto for folding the implant into the disc space. Figs. 49C,E, 50C then shows how the implant is then manipulated to a folded second configuration. Lambrecht et al. disclose the implant material can be in a woven form, paragraph 209. The examiner is interpreting the claimed elements "braided" in this way: both braided and woven are interlaced strands or filaments. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054, 1055, Figs. 50C, 50D, 51B, 51C show the implant being pulled to a folded configuration. Lambrecht also discloses the drawstring is used to pull

the implant to a folded configuration, paragraph 207. it is noted that Lambrecht et al. disclose (Figs. 27,28A) the implant **38** is positioned into the nucleus and then is formed into a second folded configuration with a multiplicity of folds. The examiner is interpreting the claimed limitations "folded configuration" with multiple folds in this way: to bend (as defined by Dictionary.com) or change in direction. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054, 1055. However, Lambrecht et al is silent as to the pulling with the drawstring results in the configuration with multiple folds. It would have been obvious to one of ordinary skill in the art the providing an implant that has a second multiple fold configuration (Fig. 27) is cable of being established in the nucleus with the method disclosed by Lambrecht of pulling (paragraphs 207,208,213) the drawstring attached at a multiplicity of sites (Fig. 49G) as it is inserted in the nucleus.

A basic premise of the foregoing analysis of Lambrecht et al. and its application to the claims as evidence of obviousness is that the claim recitation "second, folded configuration having a multiplicity of folds," given the dictionary definition of "fold" or "folded," can be reasonably construed to read on any of the implant configurations disclosed in Lambrecht, in particular, those illustrated in Figs. 50C and 51B (C-shaped configurations), Figs. 50D and 52C (L-shaped configurations), and Figs. 27 and 28A (rolled-up configurations).

Applicants respectfully submit that the Examiner's reliance upon extrinsic evidence, i.e., a general dictionary definition, for construing the terms "fold" or "folded" is improper when there is the intrinsic evidence of applicants' specification, particularly its drawings, that should control the construction to be accorded these terms. In those drawings of the subjection application showing the folded configurations of implanted lengths of natural tissue possessing a drawstring, all of the configurations can be characterized as "pleated" or "accordion like" (see, e.g., Figs. 6, 9 and 10). The

Examiner's construction of Claim 27 has totally ignored these drawings and related descriptive text to arrive at a strained and unwarranted interpretation of the claims.

However, in order to advance the prosecution of the application, applicants have amended Claim 27 to expressly recite "a second, folded configuration having a multiplicity of pleated folds." The further recitation of "pleated" in amended Claim 27 precludes any reading of the claim on the implanted configurations disclosed in the Lambrecht et al. drawings including the drawings cited by the examiner in support of the rejection.

In addition to the foregoing recitation of the term "pleated," Claim 27 has been amended with regard to the structure of the intervertebral disc device being implanted. Amended Claim 27 now recites "an intervertebral disc device comprising a length of natural tissue... and having a first end and a second end... said device additionally comprises a drawstring, said drawstring being secured to the length of natural tissue at or near the first end thereof, said drawstring passing through the tissue from one side thereof to another at a multiplicity of sites at predetermined intervals along the length of the tissue, exiting the tissue at or near the second end thereof and extending beyond said second end to terminate in an end portion for pulling the drawstring."

In none of the devices disclosed in Lambrecht et al. is there any suggestion of an implant possessing a drawstring passing therethrough from one side to another at a multiplicity of sites at predetermined intervals along its length. Lacking this feature of applicants' implantable device (see especially Figs. 9 and 10 of the subject specification in this regard), pulling on the Lambrecht et al. drawstring will not result in

applicants' "second folded configuration having a multiplicity of pleated folds" but in the non-pleated configurations of the Lambrecht et al. drawings referred to above.

In view of the foregoing amendments, Claims 17-19, 27 and 45-47 presented herein are believed to define invention which is patentable over Lambrecht et al.

The Examiner will note that the term "braided" no longer appears in Claim 27 but is now recited in new dependent Claims 49 (method) and 55 (device).

The Examiner has rejected Claim 18 under 35 U.S.C. § 103(a) as being unpatentable for obviousness over Lambrecht et al. (2002/151979) in view of Muhanna (6936070, and Claim 19 under 35 U.S.C. § 103(a) as being unpatentable for obviousness over Lambrecht et al. (2002/151979) in view of Sybert et al. (2002/107570).

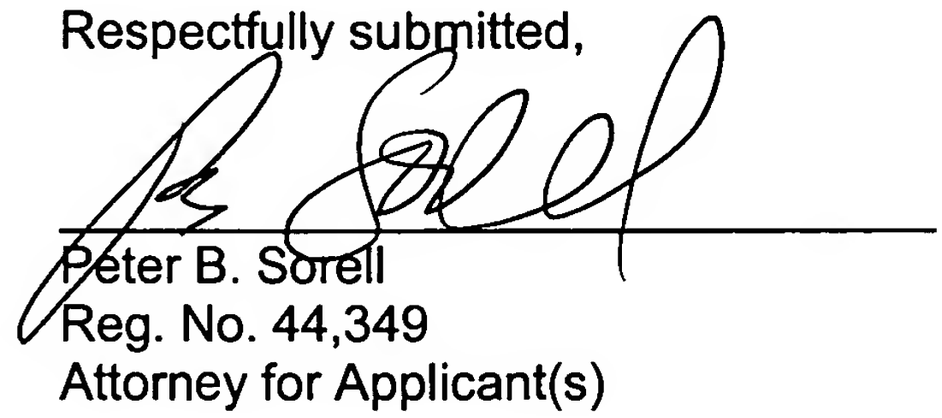
Since Claims 18 and 19 depend from amended Claim 27 which is believed to be patentable over Lambrecht et al. for the reasons presented above, these claims are also to be regarded as patentable over the combined teachings of the cited references none of which disclose or suggest a (1) method of implanting a length of natural tissue having a drawstring for placing the tissue after its implantation in an intervertebral disc nucleus in a folded configuration having a multiplicity of pleated folds or (2) the tissue with its uniquely arranged drawstring.

New claims 49 to 50, which depend from amended Claim 27, and new claims 51-58 to the implantable natural tissue device have been added to cover additional embodiments of applicants' invention.

In view of the foregoing amendment and accompanying remarks, it is respectfully submitted that all claims pending herein are in condition for allowance. Please contact the undersigned attorney should there be any questions.

Early and favorable consideration of the case is respectfully requested.

Respectfully submitted,



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